Individual Safety Report

3346185-X-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting
ealth professionals of adverse
vents and product problems

Page 3 of 3 7/1/99 clerk

Form Approved: OMB No. 0910-0291 Expires: 12/31/94
See OMB statement on reverse

FDA Use Only

Triage unit sequence # 109572

A. Patient information

1. Patient identifier: [redacted] In confidence
2. Age at time of event: 34 or Date of birth:
3. Sex: ☐ female ☑ male
4. Weight: ___ lbs 59 kgs

B. Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
   - ☐ death ___ (mo/day/yr)
   - ☐ life-threatening
   - ☑ hospitalization – initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☐ other:
3. Date of event (mo/day/yr): 6/8/99
4. Date of this report (mo/day/yr): 9/7/99
5. Describe event or problem

Suspected Drug: Acetaminophen
Reaction: Hepatitis, in setting of alchol use and unintentional Acetaminophen overdose requiring Mucomyst
PMH: hx pancreatitis, alcohol use
HPI: 34 yo M presented with abdominal discomfort x past 2 days, drank alcohol at a party and developed abdominal pain, nausea, vomiting, anorexia.
Labs: abd US 6/8- liver and spleen appear NL, pancreatic duct at UL of NL
way abd 6/7-NL, no ascites or organomegaly. On adm Hb 14.1, Hct 41, plt 150K, PT 14.9, Na 137, K 3.8, T bili 1.4H, AST 1417 H, LDH 1180H, ALT 520H, Amylase 89H, Acetaminophen level 6/8 17:40 <10
Meds: Tylenol 2 po q4h (6G per day)
Treatment: Mucomyst 70mg/kg (18.9cc) q4h x 17doses. Vitamin K 10mg SQ qd x 3 days, Pepcid 20mg IV q12h, Meperidine/Promethazine for pain. GI consult. Steroids.
Outcome: 6/11 significantly improved, 6/12 asymptomatic, discharged, was to see GI specialist in 2-3 weeks, refused to see alcohol counselor. Is not to take any Acetaminophen or alcohol. Discharge meds: Folate, Thiamine, Pepcid, Medrol dose pak

DSS

SEP 15 1999

ADVERSE EVENT REPORTING SYSTEM

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

NKA
regular alcohol use

CTU109572

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1 acetaminophen
   #2
2. Dose, frequency & route used
   #1 2 po q 4 hr
   #2
3. Therapy dates (if unknown, give duration) from/to (or best estimate)
   #1 unknown
   #2
4. Diagnosis for use (indication)
   #1 pain
   #2
5. Event abated after use stopped or dose reduced
   #1 ☑ yes ☐ no ☐ doesn't apply
   #2 ☐ yes ☐ no ☐ doesn't apply
6. Lot # (if known)
   #1 /
   #2
7. Exp. date (if known)
   #1 /
   #2
8. Event reappeared after reintroduction
   #1 ☐ yes ☐ no ☑ doesn't apply
   #2 ☐ yes ☐ no ☐ doesn't apply
9. NDC # (for product problems only)
   -
10. Concomitant medical products and therapy dates (exclude treatment of event)
    none x alcohol

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address
4. Operator of device
   - ☐ health professional
   - ☐ lay user/patient
   - ☐ other:

REC'D.
SEP 14 1999
EDWATCH CTU

6. model # ___ catalog # ___ serial # ___ lot # ___ other #
5. Expiration date (mo/day/yr)
7. If implanted, give date (mo/day/yr)
8. If explanted, give date (mo/day/yr)
9. Device available for evaluation? (Do not send to FDA)
   ☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)
10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
   [redacted] KP's [redacted] Health Care
2. Health professional? ☑ yes ☐ no
3. Occupation: MD Internist
4. Also reported to
   - ☐ manufacturer
   - ☐ user facility
   - ☐ distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☒

FDA

Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.